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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,469	03/06/2006	Sarah C Bodary	P1975R1	2209

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EXAMINER	
LI, RUIXIANG	
ART UNIT	PAPER NUMBER
1646	
MAIL DATE	DELIVERY MODE
08/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,469	BODARY ET AL.	
	Examiner	Art Unit	
	RUIXIANG LI	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/29/2005, 05/02/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Sequence alignment*

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group III (claims 12, 13, 14-17 (in part), drawn to an antibody directed to SEQ ID NO: 44) in the reply filed on 07/01/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Applicants' preliminary amendment filed upon 07/01/2008 has been entered in full. Claims 12-17 are pending and under consideration.

Objection to the Title

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. 3. In addition, the word "novel" begs the novelty of issued U. S. Patents. Any invention, when patented, is novel. There is no need to say it again in the title. It is suggested that the word "novel" be deleted from the title.

Information Disclosure Statement

4. The information disclosure statements filed on 05/02/2006 and 07/29/2005 have been considered by the Examiner. Assigned copy of form PTO-1449 is attached to the office action.

Drawings

5. The drawings filed on 03/10/2005 are accepted by the Examiner.

Claim Rejections—35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claim 12 is rejected under 35 U.S.C. §101 because the claimed invention is directed non-statutory subject matter.

Claim 12, s written, do not sufficiently distinguish over an antibody that exists naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claim should be amended to indicate the hand of the inventor, e.g., by insertion of "isolated" or "purified". See MPEP 2105.

Claim Rejections—35 USC § 112, 1st paragraph

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 12-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated antibody that specifically binds to the polypeptide of SEQ ID NO: 44, does not reasonably provide enablement for an antibody that specifically binds to a polypeptide having at least 80% amino acid sequence identity to the polypeptide of SEQ ID NO: 44. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claims 12-17 are drawn to an antibody which specifically binds to a polypeptide having at least 80% amino acid sequence identity to a polypeptide of SEQ ID NO: 44 Thus, the claims are broad and encompass antibodies that bind to a genus of variants and homologues of SEQ ID NO: 44. Since there is no functional limitation or any particular conserved structure recited in the claims, the genus encompasses an unreasonable number of inoperative polypeptides and thus antibodies, which the skilled artisan would not know how to make and/or use.

The specification merely discloses that the mRNA level of the polypeptide of

SEQ ID NO: 44 was significantly overexpressed in isolated CD4+ T cells activated by anti-CD3/ICAM-1 or anti-CD3/anti-CD28 as compared to isolated resting CD+ T cells based upon microarray analysis (Example 1; page 79, the 2nd -3rd paragraphs). There is no disclosure of any particular immune related disease that can be diagnosed or treated by the polypeptide of SEQ ID NO: 44 or the antibody that specifically bind to the polypeptide of SEQ ID NO: 44. There is no disclosure of any functional variants of the polypeptide of SEQ ID NO: 44. The instant disclosure fails to provide sufficient direction or working example on how to make and use the variants of SEQ and thus antibodies that bind to the polypeptides.

The prior art teaches an isolated polypeptide that is 100% identical to the polypeptide of SEQ ID NO: 44 of the present invention and the antibody that binds to the polypeptide (Dowling et al., U.S. Patent No.6,069,229, May 30, 2000). However, the prior art does not teach the genus of polypeptides encompassed in the instant claims and antibodies that bind to the genus of polypeptides. It is unpredictable whether a variant would retain the same function as that of the full length of polypeptide of SEQ ID NO: 14 due to lack of sufficient guidance provided in the specification and the teachings in the art on how to use those variants or homologues of the polypeptide of SEQ ID NO: 14. Without sufficient guidance, working examples, and knowledge about functions of encompassed polypeptides structurally related to SEQ ID NO: 44, it would take undue experimentation for one skilled in the art to make and use the variants of the polypeptide of SEQ ID NO: 44 and the antibodies that bind to the polypeptides, for example, in treating an immune related disease.

Accordingly, while being enabling for an isolated antibody that specifically binds to the polypeptide of SEQ ID NO: 44, the specification does not reasonably provide enablement for the antibodies that bind to the genus of polypeptides encompassed by the instant claims. Thus, it would require undue experimentation for one skilled in the art to make and use the claimed invention commensurate in scope with the claims.

Claim Rejections—35 USC § 112, 2nd paragraph

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is indefinite because it recites "a therapeutically effective amount of the antibody of claim 12". Since the specification neither defines the term unambiguously and nor shows an amount of an antibody that is effective for treatment of any particular disease, the claim is indefinite.

Claim Rejections—35 U.S.C. §102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 12-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Dowling et al. (U.S. Patent No.6,069,229, May 30, 2000).

Dowling et al. teach an isolated polypeptide of SEQ ID NO: 4 that is 100% identical to the polypeptide of SEQ ID NO: 44 (See attached sequence alignment). Dowling et al. teach an antibody that binds to the polypeptide, including a monoclonal antibody (column 25, line 3) or a single chain antibody (column 25, column 21). Dowling et al. also teach a kit comprising an antibody, a container, and instructional material for the use of the antibody (column 51, the 4th paragraph). Dowling et al. also teach a composition comprising an antibody and buffers, which are considered to be a carrier or a pharmaceutically acceptable carrier (column 38, last paragraph). Since the specification does not define the term "a therapeutically effective amount of the antibody", the examiner takes the position that any amount of the antibody satisfied the limitation. It's also noted that the limitation" wherein labeled on said container indicates that said composition of matter can be used for treating an immune related disease" is not given any patentable weight. Thus, the teachings of Dowling et al. meet the limitations of claims 12-17.

Conclusion

14. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/
Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.
August 12, 2008